

**Appl. No.** : 10/666,185  
**Filed** : September 17, 2003

### **REMARKS**

Applicants have amended certain claims in response to the Office Action. Claims 23, 26 and 29 are amended to include the scientific units for certain portions of the claim as pointed out by the Examiner in paragraph 2 of the Office Action.

Claim 23 is amended to delete the multiple dependency objection, and a new Claim 33 is added, which new claim is the same as Claim 23, but is dependent on Claim 17.

Claim 15 is rejected under 35 U.S.C. § 12, ¶ 2, as lacking antecedent basis. The claim is amended to add the word "surface" relating to the inner and outer walls, thereby obviating the antecedent language problem to which the Examiner refers.

Claims 1-11, 13, 15-22, 24-30 and 32 are rejected as unpatentable over U.S. Patent No. 4,832,034 (Pizziconi et al.) in view of European Patent Application EP '494. The rejection is respectfully traversed. Pizziconi et al. teaches a device in which an anisotropic hollow fiber membrane is inserted into a blood vessel, and water and solutes are separated from the blood through the walls of the hollow fiber membrane. The fiber membrane is described as having a thin outer skin and a thicker, porous supporting layer (see col. 38, lines 16-20). A number of figures of the patent, which are enlarged photographic views of the cross-section of a fiber according to the invention, clearly illustrate that the Pizziconi et al. fiber does not have a continuous change in mass density from the outer wall to the inner wall, nor does it comprise a continuum of voids bounded by frames, those features which are specifically recited in Applicants' claims. The Examiner turns to EP '494, alleged to teach such features as recited in Applicants' claims, the Examiner concluding that it would be obvious to substitute the hollow fiber membrane of EP '494 for those fiber membranes of Pizziconi et al. for filtering body fluids. It is submitted that the combination of references is improper under 35 U.S.C. § 103. Moreover, even if the references are combined, Applicants' invention is not taught or suggested.

The claims in the instant application recite a membrane comprising elongated hollow fibers having a continuous change in mass density from the outer wall to the inner wall and with a greater mass density at the outer fiber wall and a lower mass density along the inner wall surface, whereby the fibers are capable of separating blood plasma and toxins from whole blood within a blood vessel by passing the plasma and plasma solute through the fiber wall from the outer wall surface to the interior lumen. Although Pizziconi et al. filters blood components from

the outer wall surface to the inner lumen of the fiber, EP '494 is unrelated to such a fiber or its use. Instead, the fiber of the EP patent filters water from the inner surface of the fiber to the outer surface, exactly opposite that of either Pizziconi et al. or Applicants' fiber (see page 5, lines 1-3). Indeed, the specific effective membrane area of the EP fiber is discussed in terms of the inner surface. Moreover, the EP fibers are disclosed for the purpose of removing muddiness in tap water and processing water in the fields of fermentation and food. Accordingly, there is no teaching or suggestion whatever of using the EP fibers for any blood filtration, let alone for being inserted into the blood vessel of a patient for separating blood components. Indeed, such a filter could not be so used, since the EP membrane teaches only filtering from the inner fiber surface to the outer surface.

It is well understood that where there is no teaching or suggestion or motivation to combine references, any combination of such references under 35 U.S.C. is improper; see In re Rouffet, 47 U.S.P.Q.2d 1453; In re Fritch, 23 U.S.P.Q.2d 1780; In re Fine, 5 U.S.P.Q.2d 1596. Combining such prior references without a suggestion, teaching or motivation for the combination is simply the improper use of hindsight, as is clearly present in the instant combination of references and the rejection based on the combination. It is submitted that there is no motivation whatever of attempting to substitute the teaching of a fiber membrane for filtering muddy water or other industrial uses by filtering from the inner lumen of the fiber to the outside of the fiber, as taught by the EP reference, for a fiber membrane to be inserted into a blood vessel of a patient for separating blood components by filtering from the outside of the fiber to the inside of the fiber as taught by Pizziconi et al. If the Examiner persists in repeating the rejection based on the aforesaid combination of references, it is requested that the motivation for combining the references be pointed out.

It is submitted that even if the references are combined there is no teaching or suggestion of Applicants' claimed membrane. Assuming, for arguments sake, the references are combined as proposed by the Examiner, the fiber used in the Pizziconi et al. blood filtration would be the EP fibers. The EP fibers are characterized by requiring a critical inner "thick trunk" structure having a specific maximum diameter of 10-30  $\mu\text{m}$  as discussed on page 3, lines 18-25, of the reference. These fibers then require filtering from the thick trunk inner surface having a greater pore diameter to the outer surface having a smaller pore diameter. It is submitted that such a

**Appl. No.,** : **10/666,185**  
**Filed** : **September 17, 2003**

fiber is not capable of successfully separating blood plasma and toxins from whole blood within a blood vessel by filtering those materials through the fiber wall from the outer wall surface to the inner lumen as is required in Applicants' claims. Moreover, the resulting fiber from the Examiner's combination is a fiber having an inner filter wall characterized by critical thick trunks and that filters through the fiber from the inside to the outside. Such a fiber does not meet the fiber recited in Applicant's claims. Thus, it is submitted that the rejection of Applicants' claims by the combination of references is improper under 35 U.S.C. § 103, and should be withdrawn.

Applicants also wish to comment on the potential objection of Claim 8 under 37 C.F.R. § 1.75 as a substantial duplicate of Claim 7. Because of the different dependency of those claims, it is submitted that both are proper and are not a substantial duplicate if both claims are allowed. Claim 8 is dependent on Claim 6 which recites the specific lower mass density zone. Claim 7 is not dependent on Claim 6 so the combined limitations of Claims 7/5 do not include the lower mass density limitations.


In view of Applicants' amendments to the claims to correct the objections and the formal matters referred to in the Office Action, and since the claims are patentable over their prior art as set forth hereinabove, it is submitted the case is condition for allowance, and notification thereof is requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2/13/04

By:   
Jerry R. Seller  
Registration No. 23,051  
Attorney of Record  
Customer No. 20,995  
(619) 235-8550

S:\DOCS\JRS\URS-5443.DOC\020204